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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,463	12/06/2001	Luis Enrique Fernandez Molina	3035-102	4352

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
12/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/003,463	MOLINA ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed August 18, 2009 in response to the Office Action of February 23, 2009, is acknowledged and has been entered. Claims 1, 3-15, and 27-29 are pending. Claims 1, 3, 27, and 28 are amended. Claims 12 and 13 remain withdrawn. Claims 1, 3-11, and 27-29 are currently being examined as drawn to the elected species of low immunogenic antigen "protein", "HER-1", and "oily adjuvant".

Priority/Oath/Declaration

2. This application claims priority to and Applicants submitted the foreign priority document Cuban Patent Application No. 166/2001, filed on July 12, 2001, however Applicants noted with the foreign document submission dated April 5, 2002, that the Cuban Patent Office has changed the serial number of this Cuban Patent Application from 166/2001 to 167/2001 and Applicants stated: "It is planned to file a substitute declaration to reflect this change." It is noted that no substitute declaration has been submitted to reflect this change. Appropriate correction is required (see section 2 of the previous Office Action).

Applicants state that they are in the process of obtaining the necessary signatures for the substitute declaration. Appropriate correction is still required.

New Rejection

(necessitated by amendments)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-11, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a **vaccine** composition.

The specification contemplates use of the claimed composition for prevention and treatment of cancer, as well as the prevention and treatment of viral and bacterial diseases (p. 7, first paragraph). The specification discloses in Example 9 that mice inoculated with a composition comprising the extracellular domain of HER1 (also known as EGFR, epidermal growth factor receptor) + VSSP-GM3 + IFA were challenged with Lewis tumor cells that express HER1 and tumors did develop in the mice, although the mice lived longer than a control group inoculated with a composition comprising the extracellular domain of HER1 + CFA (Figure 5).

One cannot extrapolate the disclosure of the specification to the enablement of the claims because the specification does not provide guidance or examples for the claimed composition predictably functioning as a **vaccine**. Stedman's Medical Dictionary defines a vaccine as any preparation intended for active immunologic prophylaxis (see Stedman's Medical Dictionary, p. 1). The specification has not provided a nexus between the claimed composition and its function to prevent any disease or cancer as contemplated by the specification and as implied by the term "vaccine". Further, the specification demonstrates that a composition comprising the extracellular domain of HER1+ VSSP-GM3 + IFA failed to prevent the growth of tumors expressing HER1 *in vivo*.

Therefore, in view of the state of the art, the quantity of experimentation necessary for the claimed composition to function as a vaccine, lack of guidance in the specification for the claimed composition to predictably function as a vaccine, and the absence of working examples for the claimed composition functioning as a vaccine, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Amendment of the claims to delete “vaccine” and recite “pharmaceutical” composition would obviate the rejection.

4. All other rejections recited in the Office Action mailed February 23, 2009 are hereby withdrawn in view of amendments and arguments. The rejection of claims under 35 USC 103(a) is withdrawn in view of amendments and arguments: As Applicants stated in the remarks, pages 9-11, the references cited by Examiner exemplify protein antigens incorporated into VSSPs by chemical conjugation and as argued by Examiner, the art attributes the increased immunogenicity of the antigen to the adjuvant properties of VSSPs. The references are silent with regards to the effects of VSSPs on the immunogenicity of low immunogenic antigens when the antigens are not chemically conjugated and incorporated into VSSPs, hence, the references do not specifically teach away from such compositions. However, Applicants argue that the state of the art is such that the immunogenicity of low immunogenic antigens was known only to be potentiated by the chemical conjugation of the antigens and their incorporation into VSSPs, wherein the chemical conjugation was known to produce immunogenic

epitopes, and Applicants argue that the cited references do not teach or suggest the VSSPs could have the same potentiating effect on low immunogenic antigens not chemically conjugated and not incorporated into VSSPs. Examiner has found these arguments persuasive, hence, one of skill in the art would not be motivated to make the claimed composition and the claimed invention is not obvious over the teachings of the cited references.

5. **Conclusion:** No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642